

# Emcure

Caloshell-500 (Calcium & Colecalciferol Tablets), Module 1

## 1.6 Product Information

---

# **Emcure**

Caloshell-500 (Calcium & Colecalciferol Tablets), Module 1

## **1.6.1 Prescribing Information (Summary of Product Characteristics)**

---

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

Caloshell – 500 tablets

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

1250 mg of calcium carbonate from an organic source (Oyster shell)  
equivalent to elemental Calcium ..... 500 mg  
Colecalciferol BP..... 250 IU

For full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

**Tablet**

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Caloshell-500:

- should be used only as a therapeutic and not as a food supplement when the diet is deficient or when normal requirement of both components is increased.
- as an adjunct to specific therapy for osteoporosis or as a therapeutic supplement in established osteomalacia, pregnant patients at high risk of needing such a therapeutic supplementation or malnutrition when dietary intake is less than that required.

#### 4.2 Posology and method of administration

##### Posology

###### Adults

*Adjunctive therapy in osteoporosis:*

One tablet 2-3 times per day

*Calcium and vitamin D deficiency:*

One tablet 2-3 times per day.

##### Special Population

###### Elderly patients

*Adjunctive therapy in osteoporosis*

*Calcium and vitamin D deficiency*

Dosage as for adults.

### Paediatric population

*Calcium and vitamin D deficiency (only)*

One tablet 1-2 times per day.

### Impaired hepatic function

No dose adjustment is required.

### Impaired renal function

Caloshell-500 tablets should not be used in patients with severe renal impairment (see section 4.3).

### Method of Administration

Oral.

### **4.3 Contraindications**

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1
- Severe renal impairment (glomerular filtration rate < 30 ml/min)
- Diseases and/or conditions resulting in hypercalcaemia and/or hypercalciuria
- Renal calculi (nephrolithiasis)
- Hypervitaminosis D

### **4.4 Special Warnings and Precautions for Use**

During long-term treatment, serum calcium levels should be followed and renal function should be monitored through measurement of serum creatinine. Monitoring is especially important in elderly patients on concomitant treatment with cardiac glycosides or diuretics and in patients with a high tendency to calculus formation. In case of hypercalcaemia or signs of impaired renal function, the dose should be reduced or the treatment discontinued.

Calcium carbonate and colecalciferol tablets should be used with caution in patients with hypercalcaemia or signs of impaired renal function and the effect on calcium and phosphate levels should be monitored. The risk of soft tissue calcification should be taken into account. In patients with severe renal insufficiency, vitamin D in the form of colecalciferol is not metabolised normally and other forms of vitamin D should be used.

During concomitant treatment with other high dose sources of vitamin D and/or medications or nutrients (such as milk) containing calcium, there is a risk of hypercalcaemia and milk-alkali syndrome with subsequent kidney function impairment. In these patient's serum calcium levels should be followed and renal function should be monitored.

Calcium carbonate and colecalciferol tablets should be prescribed with caution to patients suffering from sarcoidosis because of the risk of increased metabolism of vitamin D to its active form. These patients should be monitored with regard to the calcium content in serum and urine.

These tablets should be used with caution in immobilised patients with osteoporosis due to the increased risk of hypercalcaemia.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Thiazide diuretics reduce the urinary excretion of calcium. Due to increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.

Calcium carbonate may interfere with the absorption of concomitantly administered tetracycline preparations. For this reason, tetracycline preparations should be administered at least two hours before, or four to six hours after, oral intake of calcium carbonate.

Hypercalcaemia may increase the toxicity of cardiac glycosides during treatment with calcium and vitamin D. Patients should be monitored with regard to electrocardiogram (ECG) and serum calcium levels.

If a bisphosphonate is used concomitantly, this preparation should be administered at least one hour before the intake of calcium carbonate and colecalciferol tablets since gastrointestinal absorption may be reduced.

The efficacy of levothyroxine can be reduced by the concurrent use of calcium, due to decreased levothyroxine absorption. Administration of calcium and levothyroxine should be separated by at least four hours.

The absorption of quinolone antibiotics may be impaired if administered concomitantly with calcium. Quinolone antibiotics should be taken two hours before or six hours after intake of calcium.

Calcium salts may decrease the absorption of iron, zinc and strontium ranelate. Consequently, iron, zinc or strontium ranelate preparations should be taken two hours before or after calcium carbonate and colecalciferol tablets.

Treatment with orlistat may potentially impair the absorption of fat-soluble vitamins (e.g. vitamin D3).

#### **4.6 Fertility, Pregnancy and Lactation**

##### **Pregnancy**

Calcium carbonate and colecalciferol tablets can be used during pregnancy, in case of a calcium and vitamin D deficiency. During pregnancy the daily intake should not exceed 2500 mg calcium and 4000 IU vitamin D. Studies in animals have shown reproductive toxicity with high doses of vitamin D. In pregnant women, overdoses of calcium and vitamin D should be avoided as permanent hypercalcaemia has been related to adverse effects on the developing foetus. There are no indications that vitamin D at therapeutic doses is teratogenic in humans.

##### **Lactation**

Calcium carbonate and colecalciferol Tablets can be used during breast-feeding. Calcium and vitamin D<sub>3</sub> pass into breast milk. This should be considered when giving additional vitamin D to the child.

#### **4.7 Effects on ability to drive and use machines**

Calcium carbonate and colecalciferol tablets have no known influence on ability to drive and use machines.

#### **4.8 Undesirable effects**

Adverse reactions are listed below, by system organ class and frequency. Frequencies are defined as: uncommon ( $\geq 1/1,000$ , to  $< 1/100$ ); rare ( $\geq 1/10,000$  to  $< 1/1,000$ ); very rare ( $\leq 1/10,000$ ) or not known (cannot be estimated from the available data).

##### ***Immune system disorders***

Not known: Hypersensitivity reactions such as angio-oedema or laryngeal oedema.

##### ***Metabolism and nutrition disorders***

Uncommon: Hypercalcaemia and hypercalciuria.

Very rare: Milk-alkali syndrome (frequent urge to urinate; continuing headache; continuing loss of appetite; nausea or vomiting; unusual tiredness or weakness; hypercalcaemia, alkalosis and renal impairment). Seen usually only in overdose.

##### ***Gastrointestinal disorders***

Rare: Constipation, dyspepsia, flatulence, nausea, abdominal pain and diarrhoea.

##### ***Skin and subcutaneous disorders***

Rare: Pruritus, rash and urticaria.

#### **4.9 Overdose**

##### **Symptoms**

Overdose can lead to hypercalcaemia and hypervitaminosis D. Symptoms of hypercalcaemia may include anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, polydipsia, polyuria, bone pain, nephrocalcinosis, nephrolithiasis and in severe cases, cardiac arrhythmias. Extreme hypercalcaemia may result in coma and death. Persistently high calcium levels may lead to irreversible renal damage and soft tissue calcification. Milk-alkali syndrome may occur in patients who ingest large amounts of calcium and absorbable alkali.

##### **Treatment of hypercalcaemia**

Treatment is essentially symptomatic and supportive. The treatment with calcium and vitamin D must be discontinued. Treatment with thiazide diuretics and cardiac glycosides must also be discontinued (see section 4.5). Treatment is rehydration, and, according to severity of hypercalcaemia, isolated or combined treatment with loop diuretics, bisphosphonates, calcitonin and corticosteroids should be considered. Serum electrolytes, renal function and diuresis must be monitored. In severe cases, ECG and CVP should be followed.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Mineral supplements, Calcium combinations with vitamin D and/or other drugs.

ATC code: A12AX

Vitamin D3 increases the intestinal absorption of calcium.

Administration of calcium and vitamin D3 counteracts the increase of parathyroid hormone (PTH) which is caused by calcium deficiency and which causes increased bone resorption.

A clinical study of institutionalised patients suffering from vitamin D deficiency indicated that a daily intake of calcium /vitamin D normalised the value of the 25-hydroxylated metabolite of vitamin D3 and reduced secondary hyperparathyroidism and alkaline phosphatases.

### **5.2 Pharmacokinetic properties**

#### **Calcium**

*Absorption:* The amount of calcium absorbed through the gastrointestinal tract is approximately 30% of the swallowed dose.

*Distribution and biotransformation:* 99% of the calcium in the body is concentrated in the hard structure of bones and teeth. The remaining 1% is present in the intra- and extracellular fluids. About 50% of the total blood-calcium content is in the physiologically active ionised form with approximately 10% being complexed to citrate, phosphate or other anions, the remaining 40% being bound to proteins, principally albumin.

*Elimination:* Calcium is eliminated through faeces, urine and sweat. Renal excretion depends on glomerular filtration and calcium tubular reabsorption.

#### **Cholecalciferol**

*Absorption:* Vitamin D3 is easily absorbed in the small intestine.

*Distribution and biotransformation:* Colecalciferol and its metabolites circulate in the blood bound to a specific globulin. Colecalciferol is converted in the liver by hydroxylation to 25-hydroxycolecalciferol. It is then further converted in the kidneys to the active form 1,25-dihydroxycolecalciferol; 1,25-dihydroxycolecalciferol is the metabolite responsible for increasing calcium absorption. Vitamin D which is not metabolised is stored in adipose and muscle tissues.

*Elimination:* Vitamin D3 is excreted in faeces and urine.

### **5.3 Preclinical safety data**

At doses far higher than the human therapeutic range teratogenicity has been observed in animal studies.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Starch USP NF  
Lactose Monohydrate  
Starch USPNF  
Sodium Starch Glycolate BP  
Povidone USP  
Methylparaben BP  
Purified Water BP  
Magnesium Stearate BP  
Talc BP  
Sodium Lauryl Sulphate

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

24 Months

### **6.4 Special precautions for storage**

Store in a dry place, below 25 °C. Protect from light.

### **6.5 Nature and contents of container**

10 Blister strips of 10 tablets each.

### **6.6 Special precautions for disposal and other handling**

No special requirements

## **7. Marketing authorisation holder**

Emcure Pharmaceuticals Limited  
Lane No. 3, Phase-II, SIDCO,  
Bari-Brahmana, Jammu - 181 133, INDIA

## **8. Marketing authorisation number(s)**

Not Applicable

## **9. Date of first authorisation/renewal of the authorisation**

Not Applicable

## **10. Date of revision of the text**

03<sup>rd</sup> Dec 2020

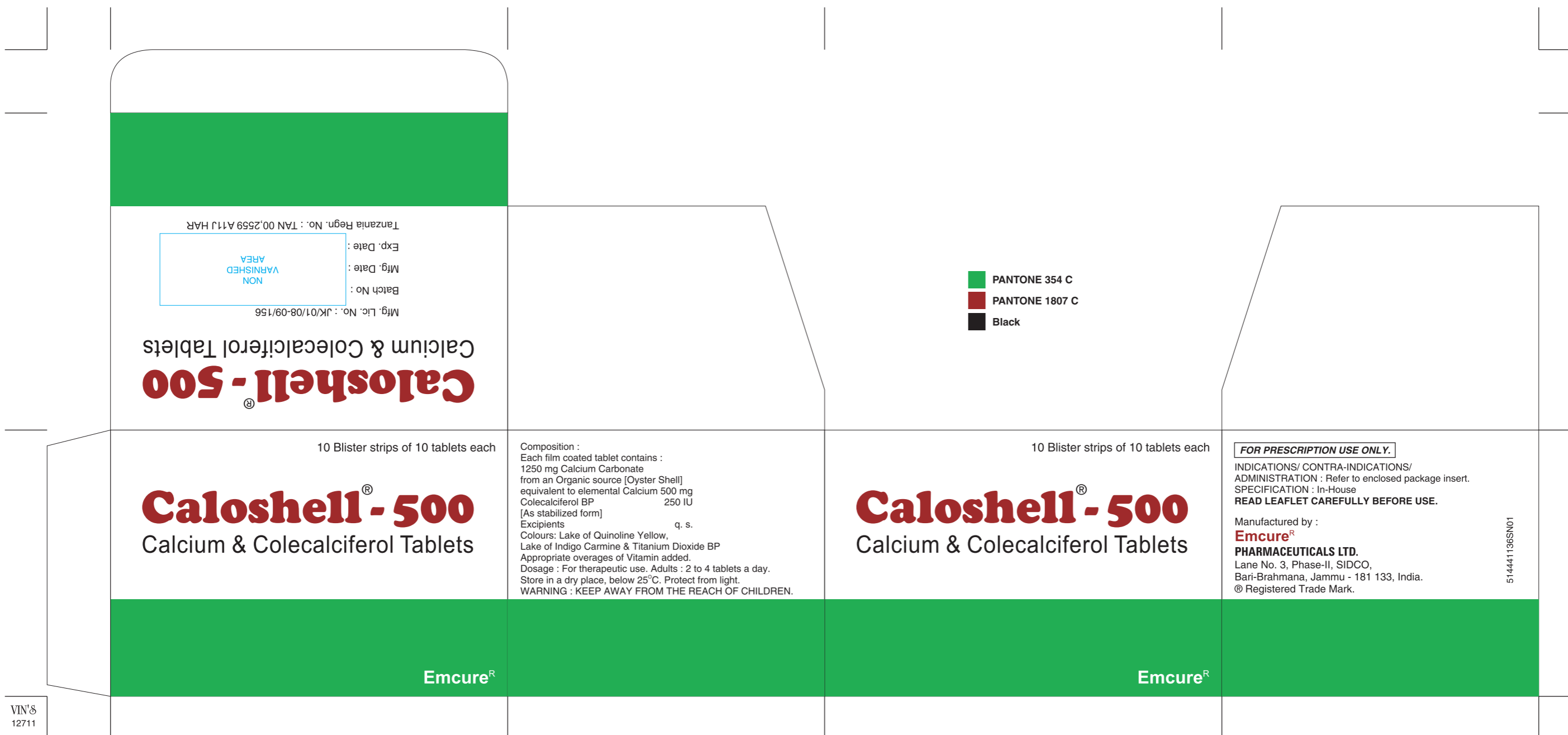


# **Emcure**

Caloshell-500 (Calcium & Colecalciferol Tablets), Module 1

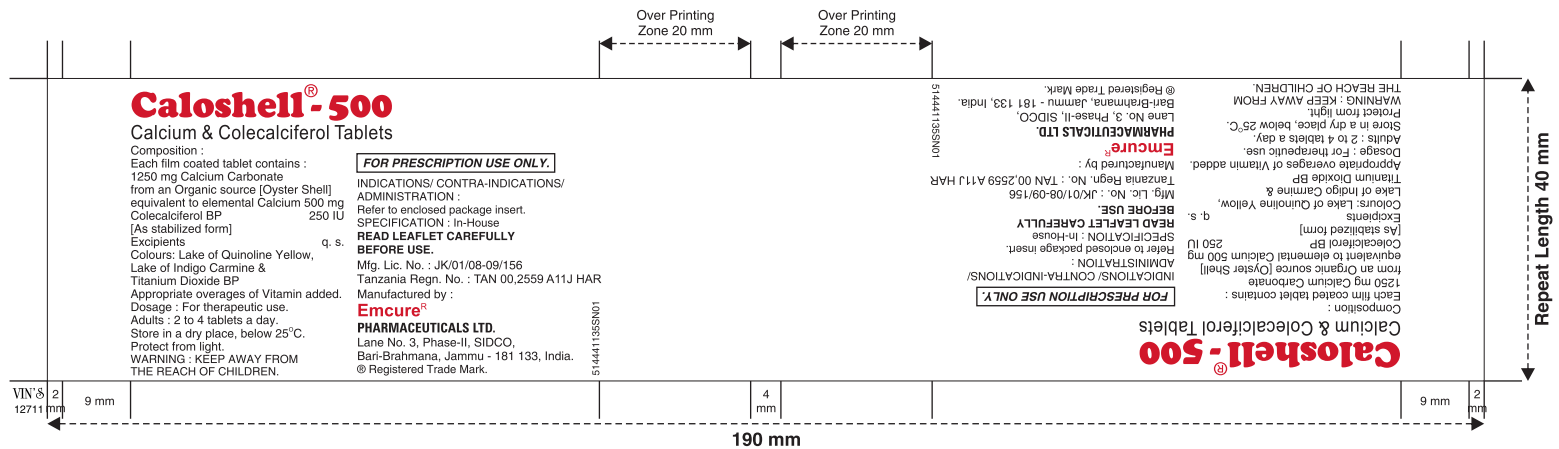
## **1.6.2 Container Labelling**

---



VIN'S  
12711

<b>Product</b>	Caloshell-500	<b>New / Revised A/W</b>	New A/W	<b>FDA Lic. Availability</b>	Avail. from
<b>Dosage form</b>	Tablet	<b>Reason for change</b>	N.A.	<b>Proof 1</b>	06.07.2011
<b>Therapeutic Category</b>	Calcium Supplement	<b>Colour Scheme</b>	Pantone	<b>Corrections of Proof 1</b>	Editorial changes
<b>Item</b>	Senegal Export Carton A/W	<b>Pantone Shades</b>	354 C, 1807 C & Black	<b>Proof 2</b>	08.07.2011
<b>Dimension</b>	L. 94 x W. 75 x H. 63 mm	<b>Total No. of Colours</b>	3	<b>Corrections of Proof 2</b>	None
<b>Substrate</b>	ITC, FBB	<b>Special Effect (if any)</b>	N.A.	<b>Proof 3</b>	N.A.
<b>Specification</b>	UV Varnished, 300 GSM	<b>Item Code</b>	514441136SN01	<b>Corrections of Proof 3</b>	N.A.
<b>Printing Area</b>	F/F	<b>Marketing Division</b>	Emcure	<b>Final</b>	12.07.2011
<b>Item Style</b>	Lock Bottom	<b>Design / Colour Approved on</b>	At the time of launching	<b>A/W Checked by</b>	PMD Cell
<b>A/W Proportion</b>	Same Size	<b>Vendor</b>		<b>A/W Verified by</b>	Production / QC
<b>Product Status</b>	Emcure Own Jammu Unit	<b>Country</b>	Senegal Export	<b>A/W Approved by</b>	Unit Head
<b>Remark (If any) :</b> New for Senegal Export					



<b>Product</b>	Caloshell - 500	<b>New / Revised A/W</b>	New A/W	<b>FDA Lic. Availability</b>	Avail. from
<b>Dosage form</b>	Tablet	<b>Reason for change</b>	N.A.	<b>Proof 1</b>	06.07.2011
<b>Therapeutic Category</b>	Calcium Supplement	<b>Colour Scheme</b>	Pantone	<b>Corrections of Proof 1</b>	Editorial changes
<b>Item</b>	Senegal Export Foil A/W	<b>Pantone Shades</b>	186 C & Black	<b>Proof 2</b>	08.07.2011
<b>Dimension</b>	190/2 mm ; RL 40 mm ; OPZ 20 mm	<b>Total No. of Colours</b>	2	<b>Corrections of Proof 2</b>	None
<b>Substrate</b>	Aluminium foil (Blister size : 91 x 59 mm)	<b>Special Effect (if any)</b>	N.A.	<b>Proof 3</b>	N.A.
<b>Specification</b>	VMCH coated 0.02 mm foil	<b>Item Code</b>	514441135SN01	<b>Corrections of Proof 3</b>	N.A.
<b>Printing Area</b>	F/F	<b>Marketing Division</b>	Emcure	<b>Final</b>	12.07.2011
<b>Item Style</b>	Continuous roll printing	<b>Design / Colour Approved on</b>	At the time of launching	<b>A/W Checked by</b>	PMD Cell
<b>A/W Proportion</b>	Same Size	<b>Vendor</b>		<b>A/W Verified by</b>	Production / QC
<b>Product Status</b>	Emcure Own Jammu Unit	<b>Country</b>	Senegal Export	<b>A/W Approved by</b>	Unit Head
<b>Remark (If any) :</b> New for Senegal Export					

For the use only by a Registered Medical Practitioner or a Hospital or a Laboratory.

## Caloshell<sup>®</sup>-500

### Calcium & Colecalciferol Tablets

#### COMPOSITION :

Each film coated tablet contains :  
1250 mg Calcium Carbonate from an Organic source  
[Oyster Shell] equivalent to elemental Calcium 500 mg  
Colecalciferol BP 250 IU  
[As stabilized form]  
Excipients q. s.

Colours: Lake of Quinoline Yellow,  
Lake of Indigo Carmine & Titanium Dioxide BP  
Appropriate overages of Vitamin added.

#### PROPERTIES :

Calcium carbonate has three main actions : it neutralizes gastric acid, supplements dietary calcium and sequesters Phosphorus in the intestine. Calcium carbonate derived from Oyster shell has higher content of elemental calcium, which is more soluble and better absorbed. Vitamin D<sub>3</sub> contained in "Caloshell " enhances calcium absorption from intestine and also helps to deposit the calcium in bones.

#### INDICATIONS :

- Pregnancy & Lactation.
- Adolescent boys & girls.
- Rickets.
- Osteomalacia
- Osteoporosis.
- Fractures.
- As supplement to prevent osteoporosis in menopausal & post-menopausal women.

#### DOSAGE :

2-4 tablets per day or as directed by the Physician.  
Dosage regimen : It is recommended as a routine supplementation from infancy to old age (including period of second half pregnancy), because of the daily need of calcium.  
However dosage will differ from case to case which will be as directed by the Physician.

#### SIDE EFFECTS :

Caloshell contains calcium carbonate derived from Oyster shell, which is easily soluble and completely absorbed, hence chances of side effects are minimum which are constipation, chalky taste in mouth.

#### CONTRAINDICATIONS :

There is no specific contraindications to caloshell, however common contraindications are

- Nausea
- Epigastric discomfort

#### DRUG INTERACTION :

Calcium carbonate may interfere with the absorption of other drugs from the gastrointestinal tract if administered concomitantly.

#### WARNING :

KEEP AWAY FROM THE REACH OF CHILDREN.

#### PRECAUTIONS :

It should be used cautiously in patients with angina pectoris, unstable angina.  
It is recommended to patients with hypercalciuria.

#### USAGE / ADMINISTRATION : Oral

**PRESENTATION :** 10 tablets in a blister strip.

**STORAGE :** Store in a dry place, below 25°C. Protect from light.

Manufactured by :

**Emcure<sup>R</sup>**  
**PHARMACEUTICALS LTD.**

Lane No. 3, Phase-II, SIDCO,  
Bari-Brahmana, Jammu - 181 133, India.  
© Registered Trade Mark.

514441137SN01

VIN'S  
13711

Product	Caloshell-500	New / Revised A/W	New A/W	FDA Lic. Availability	Avail. from
Dosage form	Tablet	Reason for change	N.A.	Proof 1	06.07.2011
Therapeutic Category	Calcium Supplement	Colour Scheme	Black	Corrections of Proof 1	Editorial changes
Item	Senegal Export Pack Insert A/W	Pantone Shades	N.A.	Proof 2	08.07.2011
Dimension	L. 80 x H. 210 mm (Folded 80 x 27 mm)	Total No. of Colours	1	Corrections of Proof 2	None
Substrate	Super white maplitho paper (J. K. Mill)	Special Effect (if any)	N.A.	Proof 3	N.A.
Specification	60 GSM	Item Code	514441137SN01	Corrections of Proof 3	N.A.
Printing Area	F/F	Marketing Division	Emcure Export	Final	13.07.2011
Item Style	N.A.	Design / Colour Approved on	At the time of launching	A/W Checked by	PMD Cell
A/W Proportion	Same Size	Vendor		A/W Verified by	Production / QC
Product Status	Emcure Own Jammu Unit	Country	Senegal Export	A/W Approved by	Unit Head
Remark (If any) : New for Senegal Export					

# **Emcure**

Caloshell-500 (Calcium & Colecalciferol Tablets), Module 1

## **1.6.3 Patient Information Leaflet**

---

## **PATIENT INFORMATION LEAFLET**

### **CALOSHELL®-500 TABLETS**

#### **calcium / colecalciferol**

**Read all of this leaflet carefully because it contains important information for you.**

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if you do not feel better or if you feel worse after two weeks.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Caloshell-500 is and what it is used for
2. What you need to know before you take Caloshell-500
3. How to take Caloshell-500
4. Possible side effects
5. How to store Caloshell-500
6. Contents of the pack and other information

#### **1. WHAT CALOSHELL-500 IS AND WHAT IT IS USED FOR**

Caloshell-500 Tablets containing calcium and vitamin D<sub>3</sub> which are both important substances in bone formation. Both are found in the diet and vitamin D is also produced in the skin after exposure to the sun.

Caloshell-500 is used to treat and prevent vitamin D/calcium deficiency, which may occur when your diet or lifestyle does not provide enough, or when body requirements are increased. This medicine may also be prescribed or recommended for certain bone conditions, for example osteoporosis, or during pregnancy.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CALOSHELL-500**

Do not take Caloshell-500 Tablets if you:

- are allergic to calcium, vitamin D, or any of the other ingredients of this medicine (listed in section 6).
- have severe kidney problems
- have a condition that causes excessive amounts of calcium in your blood or urine (hypercalcaemia or hypercalciuria) e.g.
  - renal (kidney) failure
  - cancer that has affected your bones
- have excessive amounts of Vitamin D in your blood
- have kidney stones.

## Warnings and precautions

### Talk to your doctor or pharmacist before taking Caloshell-500:

- if you have **osteoporosis** (brittle bones) and are also unable to move around
- if you are on long term treatment, especially if you are taking medicines for a **heart disorder** (cardiac glycosides), or **diuretics** (used in the treatment of high blood pressure or oedema)
- if you have signs of **impaired renal function** or a high tendency to **kidney stone** (calculus) formation
- if you have **cancer** or any other conditions that may have affected your bones.
- if you have **sarcoidosis** (an immune system disorder which may cause increased levels of vitamin D in the body).

If you have any of the following conditions your serum calcium or phosphate levels, or urinary calcium excretion must be monitored. Caloshell-500 should be taken under close medical supervision.

- **sarcoidosis** (an immune system disorder which may affect your liver, lungs, skin or lymph nodes)
- **kidney** problems
- you are on **long-term treatment** with Caloshell-500
- you are already taking **additional doses** of **calcium** or **vitamin D**.

If you have increased calcium levels in the blood or develop signs of kidney problems, the dose of Caloshell-500 should be reduced or the treatment discontinued.

### Other medicines and Caloshell-500

Please inform your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

In particular, the following medicines may interact with Caloshell-500 tablets:

- **thiazide diuretics** (water tablets); your serum calcium levels should be monitored regularly.
- **cardiac glycosides** (heart medicines); you should be monitored by electrocardiogram (ECG) and your serum calcium levels measured.
- **tetracycline antibiotics**; these should be taken at least two hours before, or four to six hours afterwards. Calcium carbonate may interfere with the absorption of tetracycline preparations if taken at the same time.
- **levothyroxine (hormone used to treat thyroid deficiency)**; these should be taken at least four hours before or after taking Caloshell-500.
- **quinolone antibiotics (ciprofloxacin, iomefloxacin, norfloxacin, sparfloxacin)**: the effect of these medicines may be reduced if taken at the same time as calcium. Take quinolone antibiotics two hours before or six hours after taking Caloshell-500.
- **bisphosphonates**; should be taken at least one hour before Caloshell-500.
- Calcium salts may decrease the absorption of **iron, zinc and strontium ranelate**. Consequently, iron, zinc or strontium ranelate preparations should be taken at least two hours before or after Caloshell-500.
- **Orlistat** (used to treat obesity) may disturb the absorption of fat-soluble vitamins, e.g. vitamin D3.

If you are taking any of the above mentioned medicines, your doctor will give you further instructions.

### Taking Caloshell-500 with food and drink

Caloshell-500 can be taken with or without food and drink.

### **Pregnancy and breastfeeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking Caloshell-500.

If you are pregnant, you may use this medicine in case of a calcium and vitamin D deficiency. During pregnancy you should not take more than 2500 mg calcium and 4000 IU vitamin D per day, as overdoses may harm the unborn child.

Caloshell-500 can be used during breast-feeding. Calcium and vitamin D<sub>3</sub> pass into breast milk. This should be considered when giving additional vitamin D to the child.

### **Driving and using machines**

Caloshell-500 has no known influence on the ability to drive or use machines.

## **3. HOW TO TAKE CALOSHELL-500 TABLETS**

Always take Caloshell-500 exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

### **Dosage**

The recommended dose is two or three tablets a day, preferably one tablet in the morning, one at midday and one in the evening.

### **Children**

The recommended dose is two tablets a day, preferably one tablet in the morning and one tablet in the evening.

### **If you take more than you should**

If you have taken more Caloshell-500 than you should, talk to your doctor or pharmacist immediately.

### **If you forget to take Caloshell-500 Tablets**

Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE-EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Stop taking your medicine and see a doctor immediately** if you experience:

- Frequent urge to urinate
- Headache
- Loss of appetite, nausea or vomiting
- Unusual tiredness or weakness, along with elevated levels of calcium in the blood and kidney impairment.

**Side effects include:**

**Uncommon side effects (may affect up to 1 in 100 people):**



- **excessive amounts of calcium in your blood** (hypercalcaemia) **or in your urine** (hypercalcuria) may occur with large doses

**Rare side effects (may affect up to 1 in 1,000 people):**

- nausea
- stomach ache
- constipation
- heartburn (dyspepsia)
- diarrhoea
- wind (flatulence)
- rash
- hives
- itching

**Very rare side-effects (may affect up to 1 in 10,000 people):**

- Milk alkali syndrome (also called Burnett's Syndrome and usually only seen when excessive amounts of calcium have been ingested), symptoms are frequent urge to urinate, headache, loss of appetite, nausea or vomiting, unusual tiredness or weakness, along with elevated levels of calcium in the blood and kidney impairment.

**Side effects with frequency not known (cannot be estimated from the available data):**

- Hypersensitivity reactions such as swelling of the face, tongue, lips (angioedema) or swelling of the throat (laryngeal oedema).
- If you have impaired renal function, you may be at risk of increased amounts of phosphate in the blood, renal stone formation and increased amounts of calcium in the kidneys.

## **5. HOW TO STORE CALOSHELL-500 TABLETS**

Keep out of the sight and reach of children.

Do not use Caloshell-500 after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month. If the tablets have changed shape or colour do not use.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Caloshell-500 Tablets contain**

**The active ingredients** in each tablet are: Calcium Carbonate [Oyster Shell], Colecalciferol [Vitamin D3]

The other ingredients are:

Starch USP NF

Lactose Monohydrate

Starch USPNF  
Sodium Starch Glycolate BP  
Povidone USP  
Methylparaben BP  
Purified Water BP  
Magnesium Stearate BP  
Talc BP  
Sodium Lauryl Sulphate

**What Caloshell-500 look like and contents of the pack**

The tablets are round, white, uncoated convex and orange flavoured; they may have small specks.

The tablets are packed in white, plastic bottles of 100 tablets.

**Marketing Authorisation Holder:**

Emcure Pharmaceuticals Limited

**Manufacturer:**

Emcure Pharmaceuticals Limited.

Lane No. 3, Phase-II, SIDCO,

Bari-Brahmana, Jammu - 181 133, INDIA

**Additional Information**

Caloshell-500 are a combination of calcium and vitamin D designed to keep bones healthy. Calcium is an essential component of bones while vitamin D plays an important role in the absorption of calcium from food.

Requirements for calcium increase with age and, although many people obtain enough calcium from their diet, some people may require a supplement in order that their body has all the calcium it needs to maintain healthy bones. Vitamin D is produced largely from the action of sunlight. Certain foodstuffs do contain vitamin D in reasonable amounts but it is not always possible to obtain all the vitamin D you need from your diet. People who do not get out and about, for instance those who are housebound or people living in nursing and residential homes, may not receive all the vitamin D they need.

People with diets and lifestyles that mean they will obtain less than the recommended intake of calcium and vitamin D are at risk of weakened bones. Prolonged lack of adequate calcium and vitamin D intake can lead to the development of osteoporosis, a condition where bones become weak

to a level that minimal trauma (for example, a fall) can result in a fracture, most typically at the hip, spine or wrist.

Caloshell-500 has been designed to give people, whose intakes of calcium and vitamin D are low, a boost to the recommended amounts.

Maintaining healthy bones and helping to avoid osteoporosis is an important issue for many people. There are many ways that people can help themselves: regular exercise, a balanced diet with an adequate intake of calcium and vitamin D and, for some people, advice on how to prevent falls which may lead to fracture.

# Emcure

Caloshell-500 (Calcium & Colecalciferol Tablets), Module 1

## 1.6.4 Mock ups & Specimens

# Emcure

Caloshell-500 (Calcium & Colecalciferol Tablets), Module 1

## 1.6.5 Information About Experts

---

## **Emcure**


Caloshell-500 (Calcium & Colecalciferol Tablets), Module 1

**1.6.5.1 Declaration signed by the Experts-  
Quality Information about Expert – Quality**

---

**Declaration Signed by the Expert – Quality****1.4.1 Quality Information**

According to his respective qualification the undersigned expert declares to have performed the duties set out in the Article 12 and in accordance with Annex I, Part I 1.4 of Directive 2001/83/EC, as amended.

**Name of the Expert** : Dr. Vikram Gharge  
**Designation** : Associate Director – R&D  
**Address** : Emcure Pharmaceuticals Limited  
R&D Centre, C- 10/12, M.I.D.C.  
Bhosari, Pune-411026.  
**Contact No.** : 020-30610000  
**Signature** :   
**Date** : 11.07.2019

According to the Annex I of Directive 2001/83/EC as amended, brief information on the Educational background, training and occupational experience of the expert is attached.

**Emcure Pharmaceuticals Limited**

C-10 (12) Functional Electronic Estate, MIDC, Bhosari, Pune - 411 026.

**Registered Office** : Emcure House, T - 184, M.I.D.C., Bhosari, Pune - 411026

Phone Nos. : +91 20 - 30610000, 40700000

E-mail corporate@emcure.co.in Website : www.emcure.co.in

CIN - U24231PN1981PLC024251

**Curriculum Vitae of the Expert**

Name	<b>Dr. Vikram S. Gharge</b>
Sex	Male
Age	38 yrs
Education Qualification	Ph.D, MS.PHARM, B.Pharm
Work Experience	Total Experience in Pharmaceutical industry is 16 years. <ul style="list-style-type: none"><li>• Chemist : Biostar Pharmaceutical Ltd, Pune,</li><li>• Scientist -I : Emcure Pharmaceutical Ltd, Pune,</li><li>• Executive: Glenmark Lab Pvt. Ltd Goa.</li><li>• Principal Scientist: Emcure Pharmaceutical Ltd, Pune.</li></ul>
Current Assignment	Principal Scientist Formulation Development, Pune. Emcure Pharmaceuticals Ltd. Pune.
Summary of Experience	Design and development of various pharmaceutical dosage forms : e.g. Tablet, Capsule, Sterile dosage form, Liquid orals, Semi solid preparations, Sustained Release dosage form, NDDS , Target drug delivery system.



## **Emcure**

Caloshell-500 (Calcium & Colecalciferol Tablets), Module 1

**1.6.5.2 Declaration signed by the Experts-  
Non- Clinical Information about the Expert – Non- clinical**

---

**Information about the Expert**

**1.4.2 Non-clinical Information**

According to her respective qualifications the undersigned expert declares hereby to have performed the duties set out in the article 12 and in accordance with Annex I, Parts I 1.4 of Directive 2001/83/EC, as amended.

**Name of the Expert** : Dr. Neha Vala

**Signature:**



**Address** : Emcure Pharmaceuticals Ltd,  
Uvarsad Square,  
Sarkhej Gandhinagar Highway,  
Adalaj, Dist. Gandhinagar, 382421  
India.

**Date** : 25-May-2020

According to the Annex I of Directive 2001/83/EC as amended , brief information on the educational back ground , training and occupational experience is attached.

The expert has written this over view at the request of the applicant. The non-clinical overview represents an independent opinion of the experts who are not subject to directives given by the applicant nor committed to her.

## EMCURE PHARMACEUTICALS LIMITED

SOP/WI No. SOP-QA-002-00	Status Final	Revision no 00	Supersedes Not Applicable
Attachment No. T-01-00	Title: Template of Curriculum Vitae (CV)		Date Effective 21-DEC-2018

CURRICULUM VITAE			
Full Name	First	Middle	Last
		Dr. Neha	Rupesh
Present position	Deputy General Manager		
Department	Pharmacovigilance and Clinical Research		
Employee Code	10013074		
Office Address	Emcure Pharmaceuticals Limited (Gandhinagar)		
Telephone Number (Country Code, Area Code, Number)	+91 79 30640153, ext: 4838.		
Email id	<a href="mailto:neha.vala@emcure.co.in">neha.vala@emcure.co.in</a>		
<b>Education/Academic Qualifications:</b> (List all colleges, Universities, Locations)			
Degree/Certification	Date (YYYY)	Institution, Country	
MBBS	2005	Sardar Patel University, Gujarat, India	
<b>Employment Experience:</b> (List all Experiences)			
Start and End Dates	Title	Institution or Company, State/Province/Country along with brief description of Job Responsibilities	
May 2018 to till date	Deputy General Manager	Emcure Pharmaceuticals Limited, Gandhinagar, Gujarat, India Job responsibility –mentioned below	
Jan 2010 to Apr 2018	Deputy General Manager	Lambda Therapeutic Research Limited, Ahmedabad, India Job responsibility-Operations In-charge and overall responsible for management of pharmacovigilance activities. Ensure compliance and quality of the pharmacovigilance activities. Serious adverse event management of clinical trials Act as medical advisor to European QPPV Handling audits and inspections Medical review of risk management plan, periodic safety reports and signal management activity	

## EMCURE PHARMACEUTICALS LIMITED

<b>SOP/WI No.</b> SOP-QA-002-00	<b>Status</b> Final	<b>Revision no</b> 00	<b>Supersedes</b> Not Applicable
<b>Attachment No.</b> T-01-00	<b>Title:</b> Template of Curriculum Vitae (CV)		<b>Date Effective</b> 21-DEC-2018

May 2008 to Dec 2009	Emergency response centre physician	GVK Emergency Management and Research Institute, Ahmedabad, India Job responsibility- online pre hospital medical advice to technician in 108 ambulance for the medical emergencies Medical emergency training of technicians
Apr 2007 to Feb 2008	Contractual medical officer	Ranbaxy laboratories Ltd., Delhi, India Job responsibility- Monitor and manage adverse reaction in study
Aug 2006 to Mar 2007	Clinical Research Physician	Lambda Therapeutic Research Limited, Ahmedabad, India Job responsibility- clinical research physician for bioequivalence studies Protocol preparation of bioequivalence study Monitor and manage adverse reaction in study Screening of the healthy volunteers
Aug 2005 to Jul 2006	Research Associate	Veeda Clinical Research, Ahmedabad, India Job responsibility- clinical research physician for bioequivalence studies Monitor and manage adverse reaction in study Screening of the healthy volunteers

**Current Job Responsibilities:**

- Act as pharmacovigilance officer in-charge or pharmacovigilance responsible person as per regulatory requirement.
- Maintain oversight on global pharmacovigilance and its quality management related functions and ensuring compliance with local regulations and company's global pharmacovigilance requirements.
- To guide and train pharmacovigilance employees to use more effective methodologies and improve efficiency. Conducting pharmacovigilance training as needed to applicable personnel of the company.
- Contributing to the on-going enhancement of Pharmacovigilance processes and preparing and reviewing of standard operating procedures related to pharmacovigilance, as needed.
- Medical review of literature articles, individual case safety reports, aggregate reports and risk management plans as needed for regulatory submissions for domestic and international markets.
- To ensure timely submissions without anything being missed out.

## EMCURE PHARMACEUTICALS LIMITED

<b>SOP/WI No.</b> SOP-QA-002-00	<b>Status</b> Final	<b>Revision no</b> 00	<b>Supersedes</b> Not Applicable
<b>Attachment No.</b> T-01-00	<b>Title:</b> Template of Curriculum Vitae (CV)		<b>Date Effective</b> 21-DEC-2018

- Providing inputs into timely response to safety related queries and product queries as needed received from different regulatory agencies, healthcare professionals and consumers for domestic and internationally marketed products.
- Provide medical conclusion for signal management activity for the company's product and keep oversight on risk minimisation activities.
- Providing support as needed for regulatory authority inspections and audits
- Provide response to pharmacovigilance related queries from various departments (formulation, regulatory, marketing)
- Provide inputs to clinical and non-clinical overviews/documents if required for domestic and international regulatory submission for US, EU & Emerging countries as per the current required regulatory guidelines.
- Provide medical inputs to the prepared Product labels (e.g. Summary of product characteristics- SmPCs) and Patient information leaflets for domestic and internationally marketed products for US, EU & Emerging countries as per the current required regulatory guidelines.
- Oversight on clinical research activities including BA-BE studies and patient based studies conducted at various CROs
- Cross functional co-ordination and support for the core functional formulation teams as well as clinical research team
- Provide inputs to protocol, reports and any other documentation of studies as necessary
- Involve in discussions between formulation, regulatory and IPR (intellectual property rights) team on weekly basis meetings or as appropriate for regulatory guidelines/requirements of product development right from pre-formulation till completion of bio-studies for regulated and semi-regulated markets
- Providing medical inputs on the team when required for any studies
- Provide approval and sign for clinical and non-clinical overview reports required during dossier application

**Trainings/Certifications:****GCP TRAINING**

- At Veeda clinical research, Ahmedabad
- Advanced and basic GCP training at Lambda Therapeutics


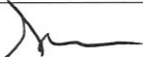
**MEDICAL**

- CPR training at V.S. hospital
- Advanced and basic life support training at Veeda clinical research.
- Advanced and basic ECG training at Veeda clinical research
- Emergency response training for 6 days at Hyderabad EMRI
- CareCon 2008 held BY EMRI at GMFC Ahmedabad.

**OTHER**

## EMCURE PHARMACEUTICALS LIMITED

<b>SOP/WI No.</b> SOP-QA-002-00	<b>Status</b> Final	<b>Revision no</b> 00	<b>Supersedes</b> Not Applicable
<b>Attachment No.</b> T-01-00	<b>Title:</b> Template of Curriculum Vitae (CV)		<b>Date Effective</b> 21-DEC-2018

<ul style="list-style-type: none"> <li>• MedDRA Training by Dr. Eliot Brown (Eliot Brown Consulting Ltd)</li> <li>• Doubling personal productivity training held by Lambda Therapeutics at AMA</li> <li>• Ahmedabad Business Etiquette training held by EMRI.</li> <li>• Business Management training held by Lambda Therapeutics</li> </ul>		
<b>Personal Details:</b>		
<b>Gender</b>	Female	
<b>Marital Status</b>	Married	
<b>Membership of Scientific Societies</b>	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/> If yes, specify or attach document Member of Ahmedabad Medical Association and Indian Medical Association	
<b>Publications</b>	No <input checked="" type="checkbox"/> Yes <input type="checkbox"/> If yes, specify or attach document	
<b>Employee's name</b>	<b>Employee's signature</b>	<b>Date</b>
Dr. Neha Vala		15 Jul 2019
<b>Line manager's name</b>	<b>Line manager's signature</b>	<b>Date</b>
Dr. Steven Hagen		15 Jul 2019

## **Emcure**

Caloshell-500 (Calcium & Colecalciferol Tablets), Module 1

**1.6.5.3 Declaration signed by the Experts-  
Clinical Information about Expert – Clinical**

**Information about the Expert****1.4.3 Clinical Information**

According to her respective qualifications the undersigned expert declares hereby to have performed the duties set out in the article 12 and in accordance with Annex I, Parts I 1.4 of Directive 2001/83/EC, as amended.

**Name of the Expert** : Dr. Neha Vala

**Signature:**



**Address** : Emcure Pharmaceuticals Ltd,  
Uvarsad Square,  
Sarkhej Gandhinagar Highway,  
Adalaj, Dist. Gandhinagar, 382421  
India.

**Date** : 25-May-2020

According to the Annex I of Directive 2001/83/EC as amended, brief information on the educational back ground, training and occupational experience is attached.

The expert has written this over view at the request of the applicant. The clinical overview represents an independent opinion of the experts who are not subject to directives given by the applicant nor committed to her.



## EMCURE PHARMACEUTICALS LIMITED

SOP/WI No. SOP-QA-002-00	Status Final	Revision no 00	Supersedes Not Applicable
Attachment No. T-01-00	Title: Template of Curriculum Vitae (CV)		Date Effective 21-DEC-2018

CURRICULUM VITAE			
Full Name	First	Middle	Last
		Dr. Neha	Rupesh
Present position	Deputy General Manager		
Department	Pharmacovigilance and Clinical Research		
Employee Code	10013074		
Office Address	Emcure Pharmaceuticals Limited (Gandhinagar)		
Telephone Number (Country Code, Area Code, Number)	+91 79 30640153, ext: 4838.		
Email id	<a href="mailto:neha.vala@emcure.co.in">neha.vala@emcure.co.in</a>		
<b>Education/Academic Qualifications:</b> (List all colleges, Universities, Locations)			
Degree/Certification	Date (YYYY)	Institution, Country	
MBBS	2005	Sardar Patel University, Gujarat, India	
<b>Employment Experience:</b> (List all Experiences)			
Start and End Dates	Title	Institution or Company, State/Province/Country along with brief description of Job Responsibilities	
May 2018 to till date	Deputy General Manager	Emcure Pharmaceuticals Limited, Gandhinagar, Gujarat, India Job responsibility –mentioned below	
Jan 2010 to Apr 2018	Deputy General Manager	Lambda Therapeutic Research Limited, Ahmedabad, India Job responsibility-Operations In-charge and overall responsible for management of pharmacovigilance activities. Ensure compliance and quality of the pharmacovigilance activities. Serious adverse event management of clinical trials Act as medical advisor to European QPPV Handling audits and inspections Medical review of risk management plan, periodic safety reports and signal management activity	

## EMCURE PHARMACEUTICALS LIMITED

<b>SOP/WI No.</b> SOP-QA-002-00	<b>Status</b> Final	<b>Revision no</b> 00	<b>Supersedes</b> Not Applicable
<b>Attachment No.</b> T-01-00	<b>Title:</b> Template of Curriculum Vitae (CV)		<b>Date Effective</b> 21-DEC-2018

May 2008 to Dec 2009	Emergency response centre physician	GVK Emergency Management and Research Institute, Ahmedabad, India Job responsibility- online pre hospital medical advice to technician in 108 ambulance for the medical emergencies Medical emergency training of technicians
Apr 2007 to Feb 2008	Contractual medical officer	Ranbaxy laboratories Ltd., Delhi, India Job responsibility- Monitor and manage adverse reaction in study
Aug 2006 to Mar 2007	Clinical Research Physician	Lambda Therapeutic Research Limited, Ahmedabad, India Job responsibility- clinical research physician for bioequivalence studies Protocol preparation of bioequivalence study Monitor and manage adverse reaction in study Screening of the healthy volunteers
Aug 2005 to Jul 2006	Research Associate	Veeda Clinical Research, Ahmedabad, India Job responsibility- clinical research physician for bioequivalence studies Monitor and manage adverse reaction in study Screening of the healthy volunteers

**Current Job Responsibilities:**

- Act as pharmacovigilance officer in-charge or pharmacovigilance responsible person as per regulatory requirement.
- Maintain oversight on global pharmacovigilance and its quality management related functions and ensuring compliance with local regulations and company's global pharmacovigilance requirements.
- To guide and train pharmacovigilance employees to use more effective methodologies and improve efficiency. Conducting pharmacovigilance training as needed to applicable personnel of the company.
- Contributing to the on-going enhancement of Pharmacovigilance processes and preparing and reviewing of standard operating procedures related to pharmacovigilance, as needed.
- Medical review of literature articles, individual case safety reports, aggregate reports and risk management plans as needed for regulatory submissions for domestic and international markets.
- To ensure timely submissions without anything being missed out.

## EMCURE PHARMACEUTICALS LIMITED

<b>SOP/WI No.</b> SOP-QA-002-00	<b>Status</b> Final	<b>Revision no</b> 00	<b>Supersedes</b> Not Applicable
<b>Attachment No.</b> T-01-00	<b>Title:</b> Template of Curriculum Vitae (CV)		<b>Date Effective</b> 21-DEC-2018

- Providing inputs into timely response to safety related queries and product queries as needed received from different regulatory agencies, healthcare professionals and consumers for domestic and internationally marketed products.
- Provide medical conclusion for signal management activity for the company's product and keep oversight on risk minimisation activities.
- Providing support as needed for regulatory authority inspections and audits
- Provide response to pharmacovigilance related queries from various departments (formulation, regulatory, marketing)
- Provide inputs to clinical and non-clinical overviews/documents if required for domestic and international regulatory submission for US, EU & Emerging countries as per the current required regulatory guidelines.
- Provide medical inputs to the prepared Product labels (e.g. Summary of product characteristics- SmPCs) and Patient information leaflets for domestic and internationally marketed products for US, EU & Emerging countries as per the current required regulatory guidelines.
- Oversight on clinical research activities including BA-BE studies and patient based studies conducted at various CROs
- Cross functional co-ordination and support for the core functional formulation teams as well as clinical research team
- Provide inputs to protocol, reports and any other documentation of studies as necessary
- Involve in discussions between formulation, regulatory and IPR (intellectual property rights) team on weekly basis meetings or as appropriate for regulatory guidelines/requirements of product development right from pre-formulation till completion of bio-studies for regulated and semi-regulated markets
- Providing medical inputs on the team when required for any studies
- Provide approval and sign for clinical and non-clinical overview reports required during dossier application

**Trainings/Certifications:****GCP TRAINING**

- At Veeda clinical research, Ahmedabad
- Advanced and basic GCP training at Lambda Therapeutics

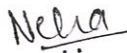
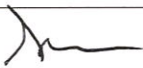
**MEDICAL**

- CPR training at V.S. hospital
- Advanced and basic life support training at Veeda clinical research.
- Advanced and basic ECG training at Veeda clinical research
- Emergency response training for 6 days at Hyderabad EMRI
- CareCon 2008 held BY EMRI at GMFC Ahmedabad.

**OTHER**

## EMCURE PHARMACEUTICALS LIMITED

<b>SOP/WI No.</b> SOP-QA-002-00	<b>Status</b> Final	<b>Revision no</b> 00	<b>Supersedes</b> Not Applicable
<b>Attachment No.</b> T-01-00	<b>Title:</b> Template of Curriculum Vitae (CV)		<b>Date Effective</b> 21-DEC-2018

<ul style="list-style-type: none"> <li>• MedDRA Training by Dr. Eliot Brown (Eliot Brown Consulting Ltd)</li> <li>• Doubling personal productivity training held by Lambda Therapeutics at AMA</li> <li>• Ahmedabad Business Etiquette training held by EMRI.</li> <li>• Business Management training held by Lambda Therapeutics</li> </ul>		
<b>Personal Details:</b>		
<b>Gender</b>	Female	
<b>Marital Status</b>	Married	
<b>Membership of Scientific Societies</b>	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/> If yes, specify or attach document Member of Ahmedabad Medical Association and Indian Medical Association	
<b>Publications</b>	No <input checked="" type="checkbox"/> Yes <input type="checkbox"/> If yes, specify or attach document	
<b>Employee's name</b>	<b>Employee's signature</b>	<b>Date</b>
Dr. Neha Vala		15 Jul 2019
<b>Line manager's name</b>	<b>Line manager's signature</b>	<b>Date</b>
Dr. Steven Hagen		15 Jul 2019